

## REMARKS

### A. Disposition of Claims

Claims 20, 22, and 23 are pending in this application. With regard to Claims 22 and 23, the terms that lack exact antecedent basis have been deleted and replaced with terms that have exact antecedent basis. Support for the amendment is found throughout the patent specification, for example, the original claims. Claims 24-26 have been canceled as being directed to methods of administering rather than methods of producing. No new matter has been added. Reexamination and reconsideration of the application, as amended, are respectfully requested.

### B. Compliance with 35 USC 112/1 - Enablement

The Patent Office maintained the rejection of the claims under 35 USC 112/1 as failing to meet the enablement requirement on the reasoning that there is no teaching in the specification nor in subsequent non-patent literature that the claimed genetic engineering method was ever attempted or if attempted was ever successful in producing phages that are capable of evading a host defense system (HDS). The rejection is respectfully traversed. The priority date of this application is April 5, 1994.

The invention solves the problem in the prior art of the use of bacteriophage to fight infections caused by bacteria. One explanation for bacteriophage not always working was because the viruses were inactivated by the host defense system. To solve this problem, the inventors developed a technology to produce bacteriophage that may be serially passaged or genetically modified to delay inactivation by the host defense system.

Using the serial passage technology, they developed long-circulating bacteriophage that are greatly superior to wild-types in terms of rescuing animals from otherwise fatal infections. These results were published as the post-filing date inventor-created art of Merrill et al., Proc Natl Acad Sci USA 93: 3188 (1996) of record.

Using the genetic engineering technique, the inventors proceeded to demonstrate that the mutation in the major phage capsid (E) protein, which resulted in the change of the acidic amino acid glutamate to the basic amino acid lysine at residue 158, conferred the "long-circulating" phenotype. The inventors identified the mutation and then incorporated this mutation into a wild-type background. These results were published as the post-filing date inventor-created art of Vitiello et al., Virus Res 114: 101 (2005), of record.

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Regarding the paragraph bridging page 3 and 4 of the Office Action about a further step of genetically engineering a bacteriophage to express a peptide on its surface coat that delays inactivation of the bacteriophage by an animal's host defense system, wherein the peptide inhibits complement activation: this further step is not antithetical to patentability, because routine experimentation can be required without violating the enablement requirement.

In short, the inventors were able to duplicate the solution to the host defense problem afforded by the serial passage technique with the genetic engineering technology. Therefore, not only is there is a teaching in the specification, which is prophetic, but also there is a teaching in subsequent non-patent scientific literature demonstrating that the claimed genetic engineering method, besides being attempted, was actually successful in producing phages that are capable of evading a host defense system (HDS).

C. Compliance with 35 USC 112/2 – Exact Antecedent Basis

The issue is whether the claims are in compliance with 35 USC 112/2 as being definite. The rule is that the claims must particularly point out and distinctly claim the subject matter that applicant regards as the invention. As requested by the Examiner with regard to Claims 22 and 23, the terms that lack exact antecedent basis have been deleted and replaced with terms that have exact antecedent basis, thus any perceived ambiguity resolved. Additionally, Claims 24-26 have been canceled as being directed to methods of administering rather than methods of producing. The conclusion is the claims are in compliance with 35 USC 112/2 as being definite.

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### CONCLUSION

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the below-given telephone number.

Respectfully submitted,

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Dated: 3/29/07

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AMEND

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